

IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

1. (currently amended) An oil-in-water lipid emulsion for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide and oligonucleotide, said emulsion comprising: 2-30% of non-triglyceride oil; 0.01-20% of one or more cationic lipid transfection agents; and water to 100%.
2. (withdrawn and currently amended) Solid[[-]] lipid nanoparticles for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide and oligonucleotide, said nanoparticles comprising: 2-30% of fat of triglycerides having 10-18 carbons in each hydrophobic tail or ethyl stearate; 0.01-20% of one or more cationic lipid transfection agents; and water to 100%.
3. (currently amended) A method of preparing an oil-in-water lipid emulsion for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide and oligonucleotide, said method comprising: a) preparing an aqueous phase by mixing 0.01-20% of one or more cationic lipid transfection agents with water and b) emulsifying said aqueous phase with 2-30% of non-triglyceride oil.
4. (withdrawn and currently amended) A method of preparing solid lipid nanoparticles for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide and oligonucleotide, said method comprising: a) preparing an aqueous phase by mixing 0.01-20% of one or more cationic lipid transfection agents with water and b) mixing said aqueous phase with 2-30% of fat of triglycerides having 10-18 carbons in each hydrophobic tail or ethyl stearate.

5. (original) The emulsion according to claim 1, further comprising 0.01-10% of a hydrophilic polymer or hydrophilic polymeric lipid.

6. (previously presented) The emulsion according to claim 1, wherein the non-triglyceride oil is squalene or squalane.

7. (previously presented) The emulsion according to claim 1, further comprising a phospholipid or a non-ionic surfactant.

8. (previously presented) The emulsion according to claim 1, wherein the cationic lipid transfection agent is selected from the group consisting of:

1,2-dimyristoyl-3-trimethylammonium-propane,
1,2-dipalmitoyl-3-trimethylammonium-propane,
1,2-distearoyl-3-trimethylammonium-propane,
1,2-dioleoyl-3-trimethylammonium-propane,
1,2-dimyristoyl-3-dimethylammonium-propane,
1,2-dipalmitoyl-3-dimethylammonium-propane,
1,2-dilauroyl-3-dimethylammonium-propane,
1,2-distearoyl-3-dimethylammonium-propane,
1,2-dipalmitoyl-3-trimethylammonium-propane,
N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride,
1,2-dioleoyl-3-ethylphosphocholine, and other cationic lipids.

9. (previously presented) The emulsion according to claim 1, further comprising glycerol or fusogenic peptides.

10. (previously presented) The emulsion according to claim 9, wherein the fusogenic peptide is polyethylene glycol of MW 500-1000 or HA gp 41.

11. (original) The emulsion according to claim 5, wherein the hydrophilic polymer is selected from the group consisting of polyoxyethylene, polyethyloxazoline and polyethyleneglycol.

12. (previously presented) The emulsion according to claim 7, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, diacetylenic phospholipid and derivative thereof and the non-ionic surface active agent is selected from the group consisting of poloxamer, sorbitan ester, polyoxyethylene-sorbitan fat acid ester and polyoxyethylene ethers.

13. (previously presented) The emulsion according to claim 1, further comprising 1,2-dioleoyl-sn-3-phosphatidylethanolamine, diolein, fatty alcohol, cholesterol or bile salt.

14. (withdrawn) The solid lipid nanoparticles according to claim 2, further comprising 0.01-10% of a hydrophilic polymer or hydrophilic polymeric lipid.

15. withdrawn) The solid lipid nanoparticles according to claim 2, further comprising a phospholipid or a non-ionic surfactant.

16. (withdrawn) The solid lipid nanoparticle according to claim 2, wherein the cationic lipid transfection agent is selected from the group consisting of:

- 1,2-dimyristoyl-3-trimethylammonium-propane,
- 1,2-dipalmitoyl-3-trimethylammonium-propane,
- 1,2-distearoyl-3-trimethylammonium-propane,
- 1,2-dioleoyl-3-trimethylammonium-propane,
- 1,2-dimyristoyl-3-dimethylammonium-propane,
- 1,2-dipalmitoyl-3-dimethylammonium-propane,
- 1,2-dilauroyl-3-dimethylammonium-propane,
- 1,2-distearoyl-3-dimethylammonium-propane,
- 1,2-dipalmitoyl-3-trimethylammonium-propane,

N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride,
1,2-dioleoyl-3-ethylphosphocholine, and other cationic lipids.

17. (withdrawn) The solid lipid nanoparticles according to claim 2, further comprising glycerol or fusogenic peptides.

18. (withdrawn) The solid lipid nanoparticles according to claim 17, wherein the fusogenic peptide is polyethylene glycol of MW 500-1000 or HA gp 41.

19. (withdrawn) The solid lipid nanoparticles according to claim 14, wherein the hydrophilic polymer is selected from the group consisting of polyoxyethylene, polyethyloxazoline and polyethyleneglycol.

20. (withdrawn) The solid lipid nanoparticles according to claim 15, wherein the phospholipid is selected from the group consisting of phosphatidylcholine; phosphatidylethanolamine, phosphatidylserine, diacetylenic phospholipid and derivative thereof and the non-ionic surface active agent is selected from the group consisting of poloxamer, sorbitan ester, polyoxyethylene-sorbitan fat acid ester and polyoxyethylene ethers.

21. (withdrawn) The solid lipid nanoparticles according to claim 2, further comprising 1,2-dioleoyl-sn-3-phosphatidylethanolamine, diolein, fatty alcohol, cholesterol or bile salt.

22. (currently amended) A complex of the emulsion according to claim 1, and a biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide, and oligonucleotide.

23. (original) The complex according to claim 22, further comprising glycolipid, lipopeptide, antibody, ligand for receptors or viral protein to target specific cells or organs.

24. (previously presented) The complex according to claim 22, further comprising protamine sulfate, histone or cationic polymer.

25. (original) The complex according to claim 24, wherein cationic polymer is polylysine.

26. (original) The complex according to claim 22, further comprising monovalent or multivalent salt.

27. (previously presented) The complex according to claim 23, wherein the cell is selected from the group consisting of white blood cells, fibroblasts, cancer cells, cells infected with virus, epithelial cells, endothelial cells, muscle cells, liver cells, endocrine cells, neural cells, dermal cells, germ cells, oocytes, sperms, hematopoietic cells, fetal cells, M cells, Langerhans islet cells, macrophages, plant cells, animal cells, and immortalized cell lines.

Claim 28 (canceled)

29. (currently amended) The complex according to claim 22, further comprising lipophilic or amphiphilic drug in an oil phase, wherein the lipophilic or amphiphilic drug is selected from the group consisting of antivirals, steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, antibiotics, antifungals, vitamins, hormones, retinoic acid, prostaglandins, prostacyclins, anticancer drugs, antimetabolitic drugs, micotics ~~mieties~~, cholinergics, adrenergic antagonists, anticonvulsants, antianxiety agents, major tranquilizers, antidepressants, anesthetics, analgesics, anabolic steroids, estrogens, progesterones, glycosaminoglycans, polynucleotides, immunosuppressants and immunostimulants.

30. (previously presented) The complex according to claim 29 wherein the anticancer drug is taxol, paclitaxel or flurouracil.

31. (withdrawn and currently amended) A complex of the solid lipid nanoparticles according to claim 2, with a biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, ~~ribosome~~, polynucleotide and oligonucleotide.

32. (withdrawn) The complex according to claim 31, further comprising glycolipid, lipopeptide, antibody, ligand for receptors or viral protein to target specific cells or organs.

33. (withdrawn) The complex according to claim 31, further comprising protamine sulfate, histone or cationic polymer.

34. (withdrawn) The complex according to claim 33, wherein the cationic polymer is polylysine.

35. (withdrawn) The complex according to claim 31, further comprising monovalent or multivalent salt.

36. (withdrawn) The complex according to claim 32, wherein the cell is selected from the group consisting of white, blood cells, fibroblasts, cancer cells, cells infected with virus, epithelial cells, endothelial cells, muscle cells, liver cells, endocrine cells, neural cells, dermal cells, germ cells, oocytes, sperms, hematopoietic cells, fetal cells, M cells, Langerhans islet cells, macrophages, plant cells, animal cells, and immortalized cell lines.

37. (withdrawn) The complex according to claim 31, wherein the complex is transferred to cells via intravenous, intramuscular, intratracheal, intranasal, subcutaneous, parenteral or topical administration or through direct administration to a specific organ.

38. (currently amended) The complex according to claim 31, further comprising lipophilic or amphiphilic drug in the fat, wherein the lipophilic or amphiphilic drug is selected from the group consisting of antivirals, steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, antibiotics, antifungals, vitamins, hormones, retinoic acid, prostaglandins, prostacyclins, anticancer drugs, antimetabolitic drugs, micotics ~~miotics~~, cholinergics, adrenergic antagonists, anticonvulsants, antianxiety agents, major tranquilizers, antidepressants, anesthetics, analgesics, anabolic steroids, estrogens, progesterones, glycosaminoglycans, polynucleotides, immunosuppressants and immunostimulants.

39. (withdrawn) The complex according to claim 38, wherein the anticancer drug is taxol, paclitaxel or fluorouracil.

40. (original) The method according to claim 3, wherein the aqueous phase further comprises 0.01-10% of a hydrophilic polymer or hydrophilic polymeric lipid.

41. (withdrawn) The method according to claim 4, wherein the aqueous phase further comprises 0.01-10% of a hydrophilic polymer or hydrophilic polymeric lipid.

42. (currently amended) A method of preparing an oil-in-water lipid emulsion for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, polynucleotide and oligonucleotide, said method comprising: a) preparing an oil phase by mixing 0.01-20% of one or more cationic lipid transfection agents with 2-30% of non-triglyceride oil and b) emulsifying said oil phase with water
~~The method according to claim 3, wherein the cationic lipid transfection agent is added in the oil phase instead of in an aqueous phase.~~

43. (withdrawn and currently amended) A method of preparing solid lipid nanoparticles for delivering biologically active material selected from the group consisting of DNA, RNA, antisense nucleic acid, polynucleotide and oligonucleotide, said method comprising: a) preparing melted fat by mixing 0.01-20% of one or more cationic lipid transfection agents with 2-30% of fat of triglycerides having 10-18 carbons in each hydrophobic tail or ethyl stearate and b) mixing said melted fat with water ~~The method according to claim 4, wherein the cationic lipid transfection agent is added in melted fat instead of in an aqueous phase.~~

44. (previously presented) The complex according to claim 29, wherein the immunosuppressant is cyclosporin A.

45. (withdrawn) The complex according to claim 38, wherein the immunosuppressant is cyclosporin A.